Prospective observational study protocol to investigate long-term adverse effects of methylphenidate in children and adolescents with ADHD: the Attention Deficit Hyperactivity Disorder Drugs Use Chronic Effects (ADDUCE) study.


Abstract

INTRODUCTION:
Methylphenidate is the most frequently used medication for the treatment of attention-deficit/hyperactivity disorder (ADHD) in Europe. Following concerns about its safety, the European Commission called for research into the long-term effects of methylphenidate on children and adolescents with ADHD. The Attention Deficit Hyperactivity Disorder Drugs Use Chronic Effects (ADDUCE) research programme was designed to address this call. At the heart of this programme is a 2-year longitudinal naturalistic pharmacovigilance study being conducted in 27 European sites.

METHODS AND ANALYSIS:
3 cohorts of children and adolescents (aged 6-17) living in the UK, Germany, Italy and Hungary are being recruited: Group 1 (Medicated ADHD): 800 ADHD medication-naive children and adolescents with a clinical diagnosis of ADHD about to start methylphenidate treatment for the first time. Group 2 (Unmedicated ADHD): 400 children and adolescents with a clinical diagnosis of ADHD who have never been treated with ADHD medication and have no intention of beginning medication. Group 3 (Non-ADHD): 400 children and adolescents without ADHD who are siblings of individuals in either group 1 or 2. All participants will be assessed 5 times during their 2-year follow-up period for growth and development, psychiatric, neurological and cardiovascular health. The primary outcome measure will be the height velocity SD score.

ETHICS AND DISSEMINATION:
Ethical approval for the study has been granted by the East of Scotland Research Ethics Service. Following this approval, patient information leaflets and consent forms were translated as necessary and submissions made by lead sites in each of the other 3 countries to their own ethics committees. Following ethical approval in each country, local ethical permissions at each site were sought and obtained as needed. The study's website (http://www.adhd-adduce.org/page/view/2/Home) provides information for researchers, participants and the general public.

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